

REMARKS

As an initial matter, Applicants would like to thank the Examiner for the opportunity to discuss the present application during the telephone interview on October 5, 2009. The present Amendment is made in furtherance of that discussion.

In response to the Final Office Action mailed June 26, 2009 and the telephone interview, claims 1, 5, 7, 8, 21, 24-26, and 74-76 have been amended. For example, claims 1 and 5 have been amended to recite a fastener apparatus that includes a body, a pledget, and a tool, rather than a fastener. The preambles of claim 7, 8, and 74-76 have been amended merely to correspond to claims 1 and 5. Claims 21 and 24-26 have been amended to recite that the leg of the fastener is bent using a tool to deform the leg.

Accordingly, claims 1, 5, 7, 8, 21-31, and 74-76 remain pending. Support for the amendments may be found throughout the original disclosure, for example, in the specification, e.g., in paragraphs [0050], [0119], and [0127]-[0129], and in the drawings, e.g., in FIGS. 1A-1C and 18-29. No new matter has been introduced.

In the Final Office Action, claims 21-26 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,002,563 (“the Pyka et al. reference”), claims 1, 27, 28, 74, and 75 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Pyka et al. reference in view of U.S. Patent No. 2,199,025 (“the Conn reference”), claims 5, 7, 8, and 76 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Pyka et al. reference in view of U.S. Patent No. 4,549,545 (“the Levy reference”), and claims 29-31 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Pyka et al. reference. Because none the cited references, either alone or in

combination, fail to disclose, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning to the Pyka et al. reference, as explained in Applicants' previous response filed August 26, 2009, shape memory alloy sutures are disclosed for suturing wounds in tissue. Col. 1, lines 5-6, col. 3, lines 3-5. For example, the suture 10 shown in FIGS. 1-4B includes a wire member 18 formed into a loop 12 with a needle 14 attached to or formed on one end 16. Col. 4, lines 59-66. FIG. 1 shows the undeformed loop configuration of the suture 10, which can be manually straightened such that, when the deforming force is removed, the suture 10 automatically returns to the loop configuration. Col. 5, lines 23-30. During use, the suture 10 is placed under sufficient stress to deform it into a deformed state that is straight enough for it to be threaded through tissue, and, as the stress is removed, the suture 10 forms the loop 12 by springing back due to its pseudoelastic nature. Col. 5, lines 33-42.

Turning to the present claims, claim 1 recites a fastener apparatus for use in surgery comprising a body having a base and a leg extending from said base; said body having a width dimension; said leg having an initial pointed end, an unformed length dimension measured from said base to said initial pointed end that is long enough to extend out of a patient when the base is in anchoring position within the patient's body, the leg configured to be cut between the base and the initial pointed end to a formed length dimension measured between said base and a new end, with the new end located between the initial pointed end and said base such that the unformed length is greater than the formed length, the leg formed from material that is deformed when the leg is bent to force the new end back towards the base to secure the fastener to tissue; a pledget

on the body adjacent the base; and a tool for bending the new end after the leg is cut to force the new end back towards the base to secure the fastener to tissue.

As explained in Applicants' previous response, the Pyka et al. reference fails to disclose, teach, or suggest a fastener having a leg formed from material that is deformed when the leg is bent to force the new end back towards the base to secure the fastener to tissue, as claimed. More particularly, the Pyka et al. reference does not teach or suggest *a tool for bending the new end* after the leg is cut *to force the new end back* towards the base to secure the fastener to tissue, as claimed. Instead, the Pyka et al. sutures are formed from shape memory material such that, when the sutures are released or cut, the sutures automatically curve or loop without use of a tool. Such shape memory materials would be incapable of being deformed using a tool to force ends of the sutures because of the pseudoelastic/ superelastic properties of the materials, as would be appreciated by a person of ordinary skill in the art. Instead, because the shape of the Pyka et al. sutures is set into the suture material, if the ends were bent using a tool after being cut, they would simply spring back to their original shape when released and not remain bent in the shape created using the tool. Further, the sutures would be incapable of being cut at any desired location along the length of the sutures without the cut ends simply springing back to their original shape.

Finally, the other cited references fail to provide any additional teaching or suggestion that may be properly combined with the Pyka et al. reference. Accordingly, for these reasons, claim 1 is neither anticipated by nor otherwise obvious over the Pyka et al. reference, either alone or in combination with the other cited references.

For similar reasons, claim 5 and its dependent claims are also not anticipated by or obvious over the cited references.

Turning to claim 21, a method is recited of placing a fastener in a patient during surgery that includes providing a fastener for use in surgery having a body having a base and a leg extending from said base, said leg having a pointed end and a length measured from said base, said length being indeterminate; locating the fastener inside a patient on one side of a tissue being operated on; driving a pointed end of the fastener through the tissue; grasping the leg after the leg has penetrated the tissue; tensioning the leg and moving the base of the fastener against the tissue; immobilizing the leg on the other side of the tissue; engaging the end of the immobilized leg; and bending the leg using a tool to deform the leg and force the end back towards the base of the fastener.

As explained above, neither the Pyka et al. reference nor the other cited references discloses, teaches, or suggests bending a leg of a fastener using a tool to deform the leg and force the end back towards a base of the fastener. Accordingly, claim 21 and its dependent claims are neither anticipated by nor otherwise obvious over the Pyka et al. reference.

For similar reasons, claims 24, 25, 26, and their dependent claims are also neither anticipated by nor otherwise obvious over the cited references.

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In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
VISTA IP LAW GROUP LLP

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By /william a. english/
William A. English
Reg. No. 42,515
Attorneys for Applicants

2040 Main Street, 9th Floor
Irvine, CA 92614
Telephone: (562) 665-3953
Facsimile: (949) 625-8955